BIOCOMPATIBLE MEMS FABRICATION

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Abstract- **Total Knee Arthroplasty (TKA) surgeries can be significantly improved with post-operative in vivo feedback to the surgeon. Strain sensors incorporated into the implant itself can introduce a new generation of artificial knees, equipping surgeons with accurate feedback of intercompartmental pressures that allow the surgeon to detect malalignment, predict polyethylene wear, and make informed revision decisions.**

Microelectromechanical Systems (MEMS) can be designed to be strain sensors in the knee. Biocompatibility of the strain sensors is a key component of sensor design; however, current semiconductor manufacturing processes are not designed to accommodate most biocompatible materials. This project examines the possibility of creating a unique fabrication process for a fully biocompatible strain sensor for use in artificial knee implants.

***Keywords* – sensors, biocompatibility, MEMS**

I. INTRODUCTION

The complexity of the knee has been a challenge for implant design and implementation in the orthopaedic industry. It is desirable to know the forces occurring in the joint compartments, prompting many researchers to focus on modeling to predict the *in vivo* forces based on external measurements. However, these modeling methods are time-consuming and many suffer high error rates. Incorporating sensors in the implant design for in vivo monitoring have been investigated to equip surgeons and implant designers with highly accurate force information. The movement of the knee requires more information than simple axial loading. Previously, instrumented implants have only accounted for the axial direction with the in-plane measurements of strain gauges and strain rosettes. However, femoral sliding, gliding, and rotation occur with respect to the tibia during normal motion. To fully characterize the loading state *in vivo*, it is proposed to use MEMS sensors to measure shear forces in addition to measuring axial forces. The small size of a MEMS sensor allows for a large array of sensors to be placed on the tibial tray or polyethylene insert to provide location specific data as well. This enables the measurement of contact areas and thus the prediction of polyethylene wear.

This project investigates the feasibility of adapting semi-conductor processing techniques with biocompatible materials, a small but essential step in the development of a sensor as described above.

II. BACKGROUND

Initial designs for instrumented implants focused on hip replacements and utilized strain gauges. In 1966, Rydell placed strain gauges on the femoral component of a hip prosthesis and passed wires through the skin for readout [1]. English, Goodman, and Kilvington used a similar setup with strain gauges, but transmitted data with an FM radio transmitter with similar findings for forces in the hip joint [2].

Bergmann, Graichen, and Rohlmann built on the concepts of using strain gauges in 1988 and have continued to refine their work through the present [3]. Their design features an inductively-powered multi-channel output sent outside the body through an RF transmitter. The patient wears the inductive coil during measurement readings. Davy and Kotzar also published work in 1988 for a strain-gauge hip prosthesis, yielding slightly lower force values during gait [4].

Bassey, Littlewood, and Taylor were the first to work on measuring femoral forces by extending the concept of the instrumented hip in 1997 and ensuing years [5]. A massive femoral implant was used with strain gauges in the distal intramedullary section to sense axial forces near the knee. Their implant was also inductively powered.

D'Lima and Colwell published information from 1996 to the present on an instrumented tibial component for measuring forces in the knee [6]. Load cells were added to the tibial tray, and the entire tibial component was separated into a top and bottom half to form 4 diaphragm "load cells" for the placement of the strain gauges. The instumented tibial tray allowed for measurement of axial forces only.

Some companies offer force sensing arrays using technology independent of strain gauges. These have been successfully used for intraoperative orthopaedic pressure sensing applications [7], but off-the-shelf components are unfit for implantation due to biocompatibility concerns, power constraints, and accuracy requirements [8].

MEMS sensors provide the ability to normal forces as well as shear and in-plane forces. Their small size can incorporate a fine spatial resolution and provide feedback about loading of the joint in various motions. Six sensors are used in a cell design that can be patterned across the implant geometry for this purpose [9].

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III. MATERIALS AND METHODS

The suitability of various biomaterials are discussed in this section, as well as the design of the sensor array and the fabrication of a test array.

A. Polyethylene

Because ultra-high molecular weight polyethylene (UHMWPE) is already present in most knee replacement designs, it is an obvious candidate for a sensor substrate. It has a dielectric constant of about 2.95 . However, UHMWPE brings up concerns with handling in common cleanroom processes, as well as adhesion concerns. Surface modification via plasma etching was investigated to improve surface adhesion during metallization. Oxygen plasma, nitrogen plasma, and oxygen/nitrogen etches were explored.

B. Parylene

The second biocompatible material considered for MEMS fabrication is poly-para-xylylene, known primarily by its trade name, parylene. Para-xylene is available in types C, D, and N (Fig. 6).

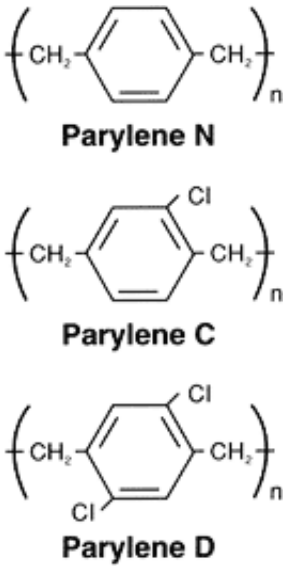

Figure 1. Types of Parylene

Parylene C (chloroxylylene) is approved by the U.S. Food and Drug Administration for multiple implantation purposes. It has been used in the semiconductor industry for its molecularly smooth surfaces that are pin-hole free. This also allows parylene to protect a metal from a corrosive environment- it is very inert. Its moisture barrier properties and gas transmission are key for sealant applications as well. Its mechanical properties are extremely predictable due to coatings free of mechanical and thermal stresses. Parylene has been used as a dielectric and as an insulator because of its superior electrical properties [10].

C. Array Design

The initial sensor cell was obtained was designed into an array using L-Edit (Tanner EDA, Monrovia, CA). Each cell contains 6 sensors to determine the complete stress state within the polyethylene insert of a knee prosthesis. Each of these sensors needed to be individually accessed while recording the position of the sensor being read. An addressing system was used to identify each individual sensor in the array. Bond pads were provided at the edges of the array connecting to each trace, with size large enough for soldering (.5 mm × .5 mm). Wire-bond pads were not used because of the concern that during the wirebond process the parylene base layer may be penetrated, yielding a broken trace/bond interface. The ends of the traces for each individual cell were enlarged so that when patterning any small error in mask alignment would still allow the traces to connect. This is also crucial for the alignment of different layers, as the interconnects need to ensure adequate signal transduction.

A soda-lime chrome mask was created with the array design on a Direct-Write Laser 66 (Heidelberg Instruments, Heidelberg, Germany).

D. Fabrication Process

All silicon wafers used were individually labeled with a diamond scribe. Twelve wafers were cleaned in a hot nanostrip bath. Four wafers underwent cleaning in a Pirhana recipe of hydrogen peroxide and sulfuric acid. A base layer of parylene was deposited onto 4 silicon wafers using 2 batches in a PDS 2010 Labcoter (SCS, Indianapolis, IN). Half a gram of dimer was used for both batches to ensure equal parylene depth. As this was a base layer, the actual thickness of the parylene layer was not crucial. However, a P10 profilometer (KLA-Tencor, San Jose, CA) was used for depth measurement of the parylene dielectric layer, which is .5 micron depth for .5 gram dimer.

Three types of polyethylene were selected for testing: high molecular weight extruded sheet, high molecular weight machined polyethylene, and compression molded medical grade polyethylene (UHMWPE). The samples were thoroughly cleaned manually using soap, deionized water, and ethanol.

The wafers and polyethylene samples then underwent standard photolithography with image reversal. A portion of the plasma-etched polyethylene samples were not patterned. A qualtitative tape test was used to roughly determine the adhesion of the gold on the various polyethylene samples. The etched polyethylene samples and the control that did not undergo gold deposition were qualitatively examined for hydrophilicity/hydrophobicity. The samples were also examined using optical microscopy and optical profilometry.

IV. RESULTS

The address system used for the cell design is shown in Figure 2. The parallel plate capacitor is A1, the two differential shear sensors are A2-3 and C1-2, respectively. Interdigitated capacitors are B2, B3, and C3.

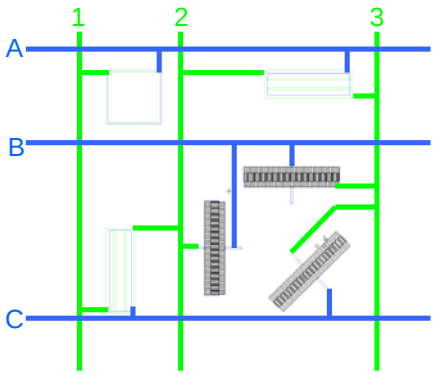

Figure 2. Example of addressing system for one sensor cell. (e.g. the parallel plate capacitor is A1, etc.)

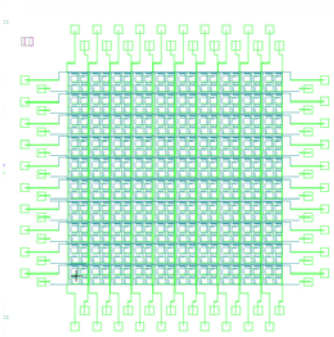

Figure 3. Test array design, 1 inch x 1 inch, with soldering pads around sides for sensor testing. In this design, only one in every 4 sensor cells is accessible for testing purposes.

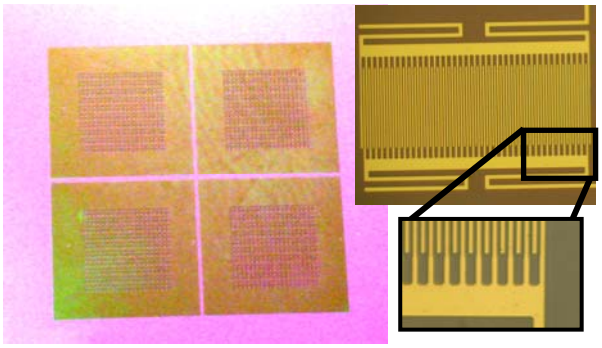

Figure 4. Layer 1 fabrication on parylene. Each cell has approximately 300 individual sensors. Inset shows one interdigitated sensor, with detail on the 2 μm spacing.

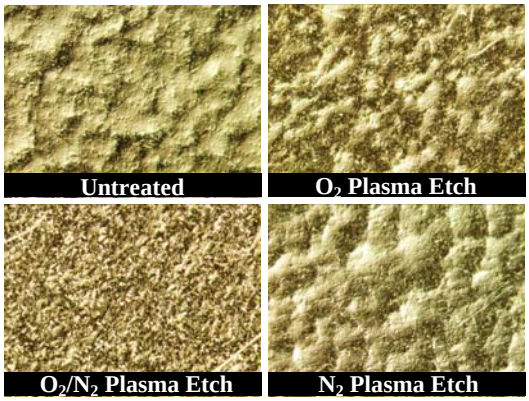

Figure 5. Thin gold layer (unpatterned) showing the optical view with various plasma treatments.

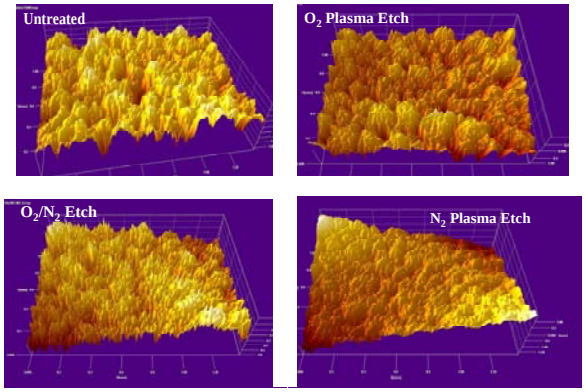

Figure 5. Profilometric view of the surface after plasma modification.

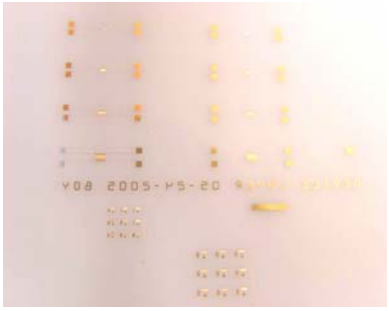

Figure 6. Most successful gold adhesion patterned on a polyethylene substrate (high density PE sheet).

Figure 5 shows the differences between plasma surface modification for the reactive ion etch processes used on the polyethylene test group. The combination nitrogen/oxygen etch showed the greatest difference in microroughening the surface, which also translated into improved gold adhesion for the samples that underwent photolithography and subsequent liftoff. The extruded high molecular weight polyethylene sheet samples performed better over the milled and compression molded samples. Only small adhesion differences between polyethylene types were observed with the tape test on the unpatterned gold-on polyethylene surfaces.

The parylene coated silicon wafers were easy to process and provided an excellent surface for photolithography. Interconnects through the parylene were formed quite easily with an oxygen plasma etch.

V. DISCUSSION

The oxygen/nitrogen etch enabled the gold to adhere somewhat to the polyethylene samples, probably because of the microroughening and functionalization of the polyethylene surface. Changes in the hydrophobicity of the surface were noticed after the various surface treatments compared to the control samples. The oxygen/nitrogen etched samples displayed both the most hydrophilicity and the most surface roughness and produced the best results for polyethylene. However, the adhesion was still not adequate for the testing of the sensors, as peeling and curling of the gold occurred on most samples. The performance of the extruded sheet polyethylene exceeded the other types of polyethylene tested primarily because it had a smoother, more uniform surface at the microscale prior to testing. For biomedical applications, we are more interested in the UHMWPE that is medical grade, which was tested as compression molded samples. It is suggested that the compression molds be even more highly polished prior to manufacture of the polyethylene samples to produce a smoother surface which can then be microroughened via plasma etch.

The parylene samples provided the best biocompatible substrate when deposited on a silicon wafer. It also provides the dielectric necessary for the sensors, and can perform adequately as an insulator and sealant in implanted devices [10]. As figure 4 shows, resolution is not a problem. However, because of the mechanical property mismatch between polyethylene currently present in knee implants and the silicon wafer used to fabricate with parylene, it is necessary to remove the parylene from the silicon substrate. Work is ongoing to test various methods of isolating the parylene without detriment to the sensor array.

VI. FUTURE WORK

The trace width, separation, and sensor layout are currently being simulated to minimize parasitic capacitance between traces that may affect sensor performance in a large array. Final sensor design will be directly above the readout electronics to yield very short z-direction traces instead of the longer horizontal and vertical leads presented here. Other flexible substrates such as polyimide and biocompatible epoxies will be investigated in the future as part of this work.

VII. CONCLUSION

Using semiconductor microfabrication technology, it is possible to modify current processes to accommodate biocompatible materials. The use of all biocompatible materials (approved by the US Food and Drug Administration) for the fabrication of a pressure sensor has been achieved. Further simulation and experimental testing are needed to optimize the fabrication of a biocompatible sensor array. Significant strides have been made in optimizing the first iteration of design and identifying areas for future concentration.

An implantable sensor array would be clinically relevant for surgeons across the globe to detect malalignment, predict polyethylene wear, and make informed revision decisions for both intra-operative and post-operative feedback for joint replacement. The potential for high accuracy and increased spatial resolution make microelectromechanical sensors a promising method of achieving these clinical goals.

VIII. REFERENCES

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